



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/511,765

05/05/2005

Marc Poirot

0505-1037

6680

466 7590 01/15/2009
YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/511,765 | Applicant(s) POIROT ET AL. | |
| | Examiner Barbara P. Badio | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-28 is/are rejected.
- 7) ☒ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/22/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits

Specification

1. The disclosure is objected to because of the following informalities: it is missing a "Brief Description of the Drawings".

Appropriate correction is required.

Claim Objections

2. Claims 7 and 8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 7 and 8 have not been further treated on the merits.

Double Patenting

3. Claims 20-25 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 19. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: The recitation of the intended use and/or property of the compound(s) does not limit the scope of the claimed compounds. Additionally, the present specification does not differentiate between the claimed compounds based on property and, thus, the

Art Unit: 1612

skilled artisan would have the reasonable expectation that the recited use/property would be applicable to the entire scope of the claimed compounds.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 22 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claims are drawn to a medicament for (a) combating human neurodegenerative diseases (claim 22) and (b) tumor regression (claim 25). The present specification provides support by showing the in vitro effect on neuritogeneses in PC 12 and PC 19 cells and in vitro/in vivo effect on mammary adenocarcinoma cells (see Examples 49, 53 and 54).

The state of the pharmaceutical art is such that screening in vitro and in vivo is utilized to determine the desired effect of pharmaceuticals. There is no absolute predictability of pharmaceuticals and, thus, one of ordinary skill in the art would not accept any therapeutic regimen on its face.

Because the pharmaceutical art is unpredictable, it requires each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d. 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is the more specific enablement is needed in order to satisfy the statute.

Here, the instantly claimed invention is highly unpredictable because the skilled artisan in the art would recognize the differences in the treatment of neurodegenerative diseases and tumors.

For example, in the medical art, it is well known that there are several different mechanisms involved in the production of cancerous/tumor cells. It is also known in the art that there are a number of sites for tumor production and, thus, there are different forms of cancers/tumors including but not limited to embryonic tumor, prostate cancer, breast cancer, giant cell tumor of bone or tendon sheath, colon cancer, lung cancer and leukemia. The prior art also teaches that because of the diversity in the pathology of

Art Unit: 1612

tumors, there are differences in treatment protocols and that there is no example of a single product that is effective in treatment of cancers/tumors in general. Thus, the skilled artisan would doubt the claimed compounds would be effective in the regression of all mammalian cancers.

Therefore, in the absence of a showing of correlation between all neurodegenerative diseases and tumors and the effectiveness of the claimed compounds in treating said conditions, one of skill in the art would be unable to fully predict the effect of administration of the claimed compounds in the combating human neurodegenerative diseases and tumor regression as encompassed by the instant claim.

As stated above, the only guidance given in the present specification is directed to (a) the in vitro effect on neuritogeneses in PC12 and PC 19 cell and (b) in vitro and in vivo effect on mammary adenocarcinoma cells, which is minimal. Thus, in order to practice the claimed invention commensurate in scope with the instant claim, the skilled artisan would have to engage in undue experimentation to determine the neurodegenerative diseases and tumors treatable by the claimed compounds, with no assurance of success.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1612

7. Claims 1-6 and 9-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

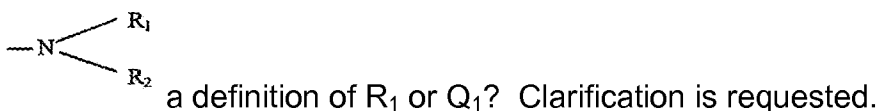
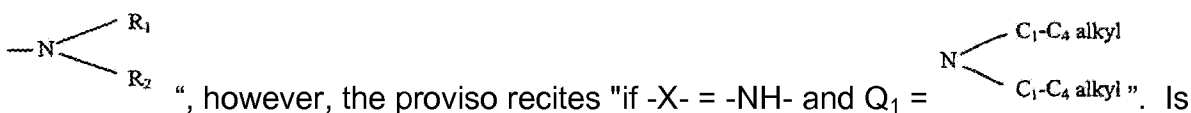
(a) Claim 1:

(i) recites "may be" in the definition of a number of variables. For example, the instant claim recites "T₁ and T₂, which **may be**, independently, H or CH₃. If not H or CH₃, what other substituent(s) can T₁ and T₂ be?

(ii) defines Z, in position 5 or 8, as either H or OH. It also states that if Z is OH, it is "borne only by a carbon that does not bear a double bond". Does applicant intend that when Z is H, it can be borne by a carbon that bears a double bond?

(iii) defines Y₁₋₅ as -S-, -O-, -C- or NR₃. Y as "C" is incomplete, i.e., the carbon atom does not have the required 4 substituents. Did applicant intend "CH₂? Correction is requested.

(iv) recites "in which R₁ represents H, COCH₃, a C₁-C₄ alkyl radical, or



(b) Claims 4 and 9 lack a period at the end.

(c) Claim 11 recites "T₁ = T₂ = T₃ = H" twice. It is requested that applicant deletion of one of said definitions.

(d) Claim 12 recites solvents A, B, C and E and activator D but lacks definition of said solvents and activator.

(e) Claim 22 recites “especially” which renders the claim indefinite because it is unclear whether the limitations following said term are part of the claimed invention.

(f) Claim 27 recites a medicament of claim 26 “taken simultaneously”. Claim 26 recites a single medicament and, thus, it is not clear how it can be taken simultaneously.

(g) Claim 21 recites nerve cells or “**precursors thereof**”. What is intended by above-mentioned phrase?

For the reasons given above, the metes and bound of the instant claims are unclear.

Claim Rejections - 35 USC § 102

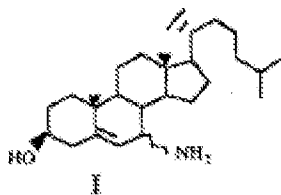
8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by El Kihel et al. (Anticancer Research, 1999).

El Kihel teaches the synthesis and cytotoxicity of aminosterols such as



(see the entire article, especially Abstract and page 1230,

Figure 1 and Table 1). The compound and composition taught by the reference are encompassed by the instant claims.

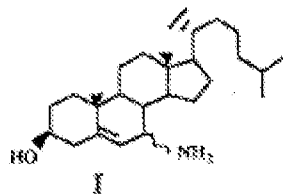
Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1 and 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over El Kihel et al. (Anticancer Research, 1999).

El Kihel teaches the synthesis and cytotoxicity of aminosterols such as



(see the entire article, especially Abstract and page

1230, Figure 1 and Table 1).

The instant claims differ from the reference by reciting the adjacent higher homolog of the compound of formula I. However, the steroid art teaches alkyl

Art Unit: 1612

substituents differing only in a single $-\text{CH}_2-$ would have similar properties. Thus, the claimed compounds would have been obvious in view of the cited reference.

Claims 26 and 27 further differ from the reference by reciting the compound is administered by injection.

Claim 28 further differ from the reference by reciting dose range of from 8.5 ng to 1.7 μg per gram of live organism.

However, (a) the art teaches various routes of administration of pharmaceuticals and (b) the determination of the amount of an active ingredient for optimum activity is routine in the pharmaceutical art. Therefore, absence a showing of the criticality of the route of administration and the dose range, the claimed invention is prima facie obvious based on the level of skill of the ordinary artisan in the art.

Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612